

REMARKS

In response to the Office Action dated 02/23/2005, please consider the following remarks made in a good faith attempt to move prosecution of this application forward to a proper allowance of the claims.

Please note that any and all fees associated with this response, including any applicable extension fees under 37 C.F.R. 1.136, may be charged to the deposit account of the undersigned, **Account. No. 50-0894**.

Applicant hereby requests such extensions under 37 C.F.R. 1.136 as may be necessary to render this response timely.

Claim Rejections

Claims 4-7 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Mak et al. (U.S. 2002/0198136 A1), and further in view of Schor et al. (U.S. 4369172).

The prior art references (the Mak and Schor patents) do not describe and do not enable the claimed invention with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention. Therefore, applicant urges the Examiner to reconsider the position that the breakthrough of the present invention – a specific dosage of the medicament at issue, administered once a day – is unobvious considering the Mak patent cited, which teaches “continuous delivery.” Even if “continuous delivery” means “delivery of said compound in longer period of time by controlled or sustained delivery system or device,” as stated by the Examiner, it is nonetheless an added burden and expense upon the many Vulvodynia sufferers. In addition, it must be realized that the more sustained the administration of any

medication, the higher the risk of side effect(s). One of the great leaps forward of the instant invention is just such a minimization of the risk of side effects.

Furthermore, the Mak patent is of the type that gives only general guidance and is not at all specific as to the particular form of the claimed invention and how to achieve it, notwithstanding the Schor patent, discussed and distinguished below. Such a suggestion by the Mak patent may make an approach "obvious to try" but it does not make the claimed invention obvious. In other words, general guidance with respect to the particular form of the invention or how to achieve it amounts to an "obvious to try" suggestion that is insufficient to support an obviousness rejection.

Furthermore, the Examiner "maintains that the determination of a dosage form or concurrent administration regimen or frequency is well within the level of one having ordinary skill in the art, and the artisan would have to be motivated to determine optimum amounts or concurrent administration regimen or frequency to get maximum effect of the drug." However, motivation to combine requires what is necessarily desirable, not merely what is feasible.

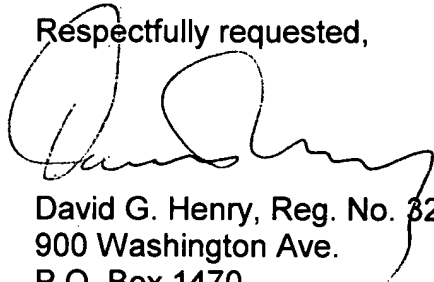
The Mak patent did not teach or suggest how to specifically deliver a specific dosage of the medicament at issue, administered once a day in a vaginal suppository form, nor did it suggest the need to do so. Therefore, the Mak patent does not render the claimed invention obvious.

The argument that the Schor patent is inapplicable is the same rationale as above. The mere fact that the Schor patent lists calcium channel blockers, including diltiazem, that can be prepared in various dosage form, including vaginal suppository form, does not render the claimed invention obvious, for the rationales described above. The Schor patent did not teach or suggest how to specifically deliver a specific dosage of the medicament at issue, administered once a day in a vaginal suppository

form, nor did it suggest the need to do so, as a composition and method for the treatment of Vulvodynia.

Applicant respectfully submits, that in view of the above, claims 4-7 are in condition for allowance. Reconsideration and withdrawal of the rejections under section 103 are hereby requested, and allowance of Claims 4-7 at an early date is solicited. If impediments to allowance of the claims remain and a telephone conference between the undersigned and the Examiner would help remove such impediments in the opinion of the Examiner, a telephone conference is respectfully requested.

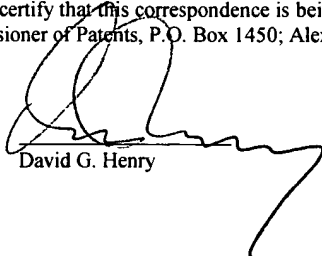
Respectfully requested,



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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450; Alexandria, VA 20231-1450, on this the 23th day August, 2005.



David G. Henry